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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

DEPOMED, INC.,

Plaintiff,

v.

PURDUE PHARMA L.P., THE P.F.
LABORATORIES, INC., PURDUE
PHARMACEUTICALS L.P.,

Defendants.

) C.A. No.:3:13-CV-00571-MLC-TJB

) Return Date: July 5, 2016

)

) **PLAINTIFF DEPOMED, INC.'S**

) **OPPOSITION TO PURDUE'S**

) **MOTION FOR LEAVE TO FILE**

) **AMENDED INVALIDITY**

) **CONTENTIONS AND**

) **CROSS-MOTION TO STRIKE**

) **PURDUE'S INVALIDITY**

) **THEORIES**

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I. INTRODUCTION

There is no good cause for Purdue's belated request in its Motion to Amend its Invalidity Contentions ("Purdue's Motion") to seek to expand the invalidity theories in the case. After Purdue's unsuccessful attempt to invalidate Depomed's Patents in the various *inter partes* review ("IPR") proceedings it initiated, Purdue manufactured "new" invalidity claims that Purdue knew of when it served its invalidity contentions. Purdue's attempt to expand its invalidity case is contrary to its numerous representations that a stay pending the IPR proceedings would streamline the invalidity issues in this case and that Purdue would be estopped in the litigation from asserting defenses it raised or could have raised to the PTAB.

For example, there is no justification for attempting to amend its invalidity contentions to add an indefiniteness allegation, which Purdue could have raised earlier, but failed to do so. Purdue should also be barred from adding "new" invalidity theories that it did not specifically address in its invalidity contentions, which Purdue was well aware of years earlier. Furthermore, the PTAB ultimately declined to institute IPR review based on these purported "new" combinations. Thus, there is no justification to introduce additional invalidity theories.

Depomed will suffer prejudice if Purdue is allowed to expand its invalidity case at this time. Depomed will have to seek fact and expert discovery into these additional issues, and will incur additional expense and time, after already dealing

with Purdue's unsuccessful IPRs. Depomed also anticipates that Purdue will use any grant that permits it to add claims into the case as a basis for further delaying the case schedule. Depomed has already faced an almost two year delay in the litigation. The Court granted Purdue's stay requests based upon Purdue's numerous representations that the IPRs will narrow the invalidity issues and the IPR proceedings would promote efficiency and simplify the case. It would be unduly prejudicial to require Depomed to defend against an expanded invalidity case after defeating Purdue's IPRs, particularly given Purdue's representations.

Finally, Depomed cross-moves to strike Purdue's invalidity theories under 35 U.S.C. §§ 102 and 103 for the same reasons above, as well as the fact that Purdue's invalidity claims are (1) deficient, (2) not previously disclosed, and/or (3) should now be barred from the litigation. For the foregoing reasons, and as discussed below, Depomed seeks an order denying Purdue's Motion for Leave to Amend and an order striking Purdue's invalidity contentions under 35 U.S.C. §§ 102 and 103.

II. STATEMENT OF FACTS

A. Procedural Background

On January 29, 2013, Depomed filed a complaint against Purdue for infringement of three patents, including the '475 and '280 Patents. Dkt. 1. On July 23, 2013, Depomed amended its complaint pursuant to Rule 15(a)(1) of the

Federal Rules of Civil Procedure, adding claims of infringement of an additional patent. Dkt. 49. Pursuant to Local Patent Rules 3.3 and 3.4, in September of 2013, Purdue served its Invalidity Contentions and Depomed's served its responses to those Invalidity Contentions. Dkt. 47. A few months later, on January 24, 2014, Purdue filed its petitions for IPR before the PTAB (discussed in detail below) based on the same prior art Purdue disclosed in its Invalidity Contentions. Dkt. 71.

While Purdue's IPR requests were pending, certain discovery was stayed so the parties could focus on mediation. Dkt. 73. Purdue did not seek to stay the entire litigation until April of 2014. Dkts. 76-77. The Court issued an order on July 29, 2014 staying the litigation pending final decisions on the IPRs. *See* Dkt. 85.

Just a few days before filing its IPR requests, Purdue exchanged a list of proposed claim terms for construction with Depomed on January 22, 2014. Ex. 1. In this exchange, Purdue proposed the "substantially all" terms to be construed, even though, several weeks earlier, on January 10, 2014, the Supreme Court granted certiorari in *Nautilus, Inc. v. Biosig Instruments, Inc.* 134 S.Ct. 2120 (2014). The Supreme Court issued the *Nautilus* opinion on June 2, 2014. Purdue first raised this claim, however, nearly two years later on May 20, 2016, in response to Depomed's decision to seek to strike Purdue's invalidity theories pursuant to 35 U.S.C. §§ 102 and 103. Ex. 5.

B. Purdue's IPRs and Multiple Requests to Stay the Litigation

In its IPR petitions, Purdue raised a variety of anticipation and obviousness theories in light of the following references: Colombo, Baveja, Kim, the '453 Patent, the '803 Patent, the '548 Patent, and the '837 Patent. Dkt. Nos. 85-1, 85-2, and 85-3. As Purdue informed the Court in its May 5, 2014 brief, the IPRs were supposed to at a minimum, "substantially narrow the issues," because Purdue would have "distinct advantages" with its IPR challenges of invalidity before the PTAB. Dkt. No. 83 at 3. Specifically, Purdue had a lower burden of proof before the PTAB because there is no presumption of validity at the IPR stage and claim terms are given the "broadest reasonable construction." Dkt. No. 83 at 3 ("Second, the burden of proof in an IPR is a preponderance of the evidence with no presumption of validity. 35 U.S.C. § 316(e). Third, claims terms may be given a somewhat broader construction in an IPR ('broadest reasonable construction'). 37 C.F.R. § 42.100(b)"). Applying these standards, the PTAB instituted trials based on certain obviousness theories based on these references and rejected Purdue's claims that these references could anticipate Depomed's Patents. Dkt. No. 85-1 at 25; Dkt. No. 85-2 at 25; Dkt. No. 83 at 22. Specifically, the PTAB rejected Purdue's claims that Baveja, Colombo or the '837 patent could anticipate any of Depomed's patent claims. Dkt. No. 85-1 at 10, 13,16; Dkt. No. 85-2 at 10, 13.

The PTAB also found that Purdue had not shown a reasonable likelihood that it would prevail as to the unpatentability of certain claims based on certain combinations of the prior art references Purdue asserted. Dkt. No. 85-1 at 25; kt. No. 85-2 at 24; Dkt. No. 85-3 at 21. It determined that Purdue failed to show the unpatentability of claims 11 and 12 over the combination of Baveja, the '453 Patent, and in view of the '837 Patent, and further in view of the '548 Patent because there was no proof that the '453 Patent was prior art under 35 U.S.C. § 102(a), (b), or (e). Dkt. No. 85-1 at 23-24; Dkt. No. 85-2 at 21-22. The PTAB also found that the obviousness challenges that Purdue now seeks to raise here redundant, for all but Claims 11 and 12. *See* Dkts. 85-1 at 25; 85-2 at 24; 85-3 at 21 (2014-7-10 Decisions to Institute). On these grounds, the PTAB did not institute the following obviousness claims: (a) Claim 10 of the '475 and '280 Patents, based on a combination of Colombo, Kim, the '837 patent and the '548 patent, (b) Claims 1, 8, 9, 13, 14, 45, and 46 of the '280 Patent based on a combination of Colombo, the '837 patent and the '548 patent, (c) Claims 43, 54, 55, 57, 58, and 66, of the '475 Patent based on a combination of the '803 patent, Baveja, and Colombo.

On July 8, 2015, the PTAB issued three separate final decisions, confirming the validity of all the claims at issue in the IPRs of the Patents-in-Suit over

Purdue's asserted (and alleged) prior art. Dkt. 98, Exs. A-C. The Federal Circuit confirmed the PTAB's validity finding on March 4, 2016. Dkt. 115.

During the pendency of the IPRs, the Court instituted a complete stay of the litigation for almost two years, from July 29, 2014 until March 31, 2016. *See, e.g.*, Dkts. 71, 77, 83, 85, 90, 91, 98, 104, 106, 108, 112, 115 and 117. The Court reasoned that while "staying any case pending IPR review by the PTAB naturally risks prolonging the final resolution of the pending case," the IPR proceedings will have an estoppel effect on Purdue as "Purdue will be estopped from asserting in this litigation any prior art that it asserted or reasonably could have asserted in the IPRs." Dkt. No. 89. This reasoning was based on Purdue's numerous representations that the IPRs will streamline the invalidity issues in the case.

For example, on February 6, 2014 and April 11, 2014, Purdue explicitly stated that "[e]ven if the Patent Office was to affirm the validity of all claims of the '475 and '280 Patents, the issues for trial in the present action would be simplified because Purdue would be estopped from relitigating the validity of those claims...." Dkt. No. 71 at 3, Dkt. No. 76 at 3. In a subsequent May 5, 2014 brief, Purdue explicitly briefed an argument entitled "Purdue's IPRs Will Eliminate All Issues or, At Minimum, Substantially Narrow The Issues." Dkt. No. 83 at 3. In this argument, Purdue insisted that "[e]ven if one or more claims survive IPR, the issues will have been substantially narrowed" because "following a final decision

in the IPRs, Purdue will be estopped from asserting in the litigation any prior art that is asserted or could have been asserted in the IPRs.” Dkt No. 83 at 3. Purdue repeated this argument in its subsequent July 21, 2014 briefing, in which Purdue unequivocally argued that “the IPRs will simplify this case by either invalidating up to 25 of the asserted claims or, even if one more claims survive IPR, estopping Purdue from raising certain invalidity arguments with respect to the surviving claims.” Dkt. No. 88 at 2.

Purdue also argued in a July 11, 2014 brief that IPRs would simplify the validity issues as to Claims 11 and 12 of Depomed’s Patents because “they include all the same limitations as [Claim 1 of the ‘475 Patent and Claim 1 of the ‘280 Patent]” which the PTAB “found a reasonable likelihood that Purdue would be able to establish invalidity.” Dkt No. 85 at 1-2. Purdue emphasized again in its July 21, 2014 briefing that “[I]n any event, the PTAB’s resolution of invalidity of the claims from which claims 11 and 12 depend will plainly simplify any remaining validity issues for claims 11 and 12.” Dkt No. 88 at 3.

Purdue also requested and was granted a stay pending resolution of issues of validity and infringement of the ‘475 and ‘280 Patents, which were asserted against different defendants, Endo and Actavis, in other non-related proceedings. Dkt. 83, 104. On August 18, 2014, Judge Pisano of the District of New Jersey found the ‘475 and ‘280 Patents valid and infringed. *See Depomed, Inc. v. Actavis Elizabeth*

LLC, No. 12-1358-JAP, Dkt. Nos. 376, 383 (D.N.J. Aug. 19, 2014, Aug. 25, 2014), attached as Exs. 2, 9 to the Declaration of Yuridia Caire in Support of Depomed's Opposition ("Caire Decl.") filed herewith. On September 23, 2015, the validity of all asserted claims of the '475 and '280 Patents were further confirmed in IPR proceedings initiated by Endo. *See Depomed, Inc. v. Endo Pharm., Inc.*, No. 13-2467-MLC-TJB, Dkt. No. 56 (D.N.J. Sept. 28, 2015) (Caire Decl., Ex. 3).

C. Case Schedule

The parties met and conferred and jointly submitted a proposed case schedule on April 12, 2016. Dkt. 118-1. On April 19, 2016, Depomed requested that Purdue confirm that Purdue was no longer pursuing any invalidity theories for the '475 and '280 Patents based on 35 U.S.C. §§ 102 and 103 specifically identified in its invalidity contentions. Caire Decl., Ex. 4. The parties met and conferred and Depomed informed Purdue that it would move to strike Purdue's invalidity challenges under §§ 102 or 103. *Id.*, Ex. 5 at 2-3. In response, on April 20, 2016, Purdue submitted its preliminary claim constructions, indicating for the first time that it was asserting that the term "substantially all of said drug" is indefinite. *Id.*, Ex. 6. Thereafter, on May 20, 2016, Purdue raised for the first time that it would move to amend its contentions in view of *Nautilus* and identified for the first time various new invalidity theories under §103 that it would assert in the case. *Id.*, Ex. 5. These new theories, however, were ones that Purdue agreed it

would *not* be pursuing in the litigation. Specifically, years earlier, in 2013 after Purdue served its invalidity contentions, Purdue agreed that the combinations that it would be pursuing in the litigation were only those that were specifically disclosed and discussed in its invalidity contentions. *Id.*, Exs. 7-8. Its other general disclosures were not intended to be invalidity theories that Purdue was going to pursue. *Id.* Based on this representation, Depomed did not seek to strike Purdue's invalidity contentions at the time they were served in 2013.

III. PURDUE HAS NO GOOD CAUSE TO JUSTIFY ITS REQUESTED AMENDMENT AND FAILS TO ADDRESS THE RESULTING UNDUE PREJUDICE TO DEPOMED

Purdue can only amend its invalidity contentions by order of the court upon a timely application and a showing of good cause. L. Pat. R. 3.3. Purdue is also required to demonstrate that there would not be undue prejudice to Depomed. L. Pat. R. 3.7. There is no good case to permit Purdue to amend its invalidity contentions and Purdue made no meaningful effort to address the undue prejudice that Depomed will face if such an amendment is granted. For this reason, district courts do not liberally grant motions to amend invalidity because “the philosophy behind amending claim charts is decidedly conservative and designed to prevent the ‘shifting sands’ approach,’ to a party’s contentions.” *Nautilus Neurosciences, Inc. v. Wockhardt USA, LLC*, No. 11-1997 (ES) (SCM), 2013 WL 7901901, at *2 (D.N.J. Jan 23, 2013) (citation and internal quotations omitted).

Purdue's Motion is allegedly based on the Supreme Court decision in *Nautilus*, which Purdue contends changed the indefiniteness standard. Purdue, as the moving party, has the burden of demonstrating its diligence in discovering and raising its indefiniteness theory, which it cannot do. *See, e.g., Warner Chilcott Co. v. Mylan Inc.*, No. 13-6560 (MLC), 2015 WL 3630970, at *4-6 (D.N.J. June 10, 2015) (denying motion to amend where defendants were not diligent in uncovering the proposed new prior art and related arguments). Purdue has no good cause to add this invalidity theory because (1) *Nautilus* did not change the relevant inquiry on definiteness and there was no recent discovery of prior art that justifies Purdue's attempts to add new obviousness combinations (which is what Purdue is effectively seeking by requesting a "ruling" on certain theories), (2) Purdue was not diligent because it could have raised such new theories earlier, and (3) Depomed would suffer undue prejudice if Purdue is permitted to add these new theories after the case was stayed for over two years at Purdue's request.

A. Purdue Lacks Good Cause

1. *Nautilus* Did Not Change the Relevant Inquiry for Indefiniteness.

There was nothing in *Nautilus* that was a "sea change" regarding the law of definiteness, and the relevant inquiry for indefiniteness remains the same. To be sufficiently definite, a patent specification must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the

applicant regards as the invention.” 35 U.S.C. § 112(b). Consistent with the language of the statute, the *Nautilus* decision held that “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus*, 134 S.Ct. at 2124. Moreover, *Nautilus* did not address or change the requirements for definiteness for words of degree, such as the claim language at issue, “substantially all of said drug,” which appears in the ‘475 and ‘280 Patents. See *In re Maxim Integrated Prods., Inc.*, No-12-244, 2014 WL 3696137, at *11 (W.D. Pa. July 23, 2014) (while the patent in *Nautilus* included a similar phrase, “produce a substantially zero,” signal, *Nautilus* did not address or change the law with respect to the standard for indefiniteness for words of degree) (citing *Nautilus*, 134 S.Ct. at 2126).

In fact, *Nautilus* is consistent with the pre-existing definiteness law, namely the requirement that the claims need to inform one skilled in the art about the scope of the invention with reasonable certainty. 134 S. Ct. at 2129 (holding that “a patent must be precise enough to afford clear notice of what is claimed, thereby ‘appris[ing] the public of what is still open to them’” but recognizing that “absolute precision is unattainable”) (citation omitted). District court opinions issued after *Nautilus* demonstrate that while the *Nautilus* standard for indefiniteness “may invalidate some particularly ambiguous patents that may have survived the

previous test, the *relevant inquiry* remains the same: whether or not a skilled artisan at the time of the patent application would construe the patent’s claim with sufficient definiteness.” *Bos. Sci. Corp. v. Cook Inc.*, No. 1:10-cv-11646-DPW, 2016 WL 1627601, at *14 (D. Mass. Apr. 22, 2016) (emphasis added) (finding *Nautilus* did not change the end result regarding its definiteness determination) (citation and internal quotation omitted); Ex. 9 at 95 (D.N.J. Aug. 25, 2014) (finding the claim meaning for the ‘280 Patent is discernible after *Nautilus*). In fact, claim language employing terms of degree, such as the “substantially all” language of the Depomed Patents, “has long been found definite where it provides enough certainty to one of skill in the art when read in the context of the invention.” *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364 , 1370 (Fed. Cir. 2014). For example, the court in *In re Maxim*, in deciding a motion to reconsider its previously issued claim construction in light of the *Nautilus* decision, found that the term “substantially unique” would remain definite under *Nautilus*. *See In re Maxim*, 2014 WL 3696137, at *11.

2. Several District Courts, Purdue and the PTAB Were Able to Construe the Term “Substantially” Recited in Depomed’s Patents

Particularly compelling is the fact that four different courts, including one in this district, have construed the claim term “substantially” recited in the ‘475 and ‘280 Patents. Specifically, Judge Hamilton construed “releases substantially all of

said drug within about eight hours after such immersion” and “substantially intact” in *Depomed, Inc. v. Lupin Pharm., Inc.*, No. C-09-05587 PJH, Dkt. No. 107 at 15-16, 23 (N.D. Cal. May 17, 2011) (Caire Decl., Ex. 10). Judge Breyer construed “substantially all of said drug” in *Depomed, Inc. v. Ivax Corp.*, No. C-06-00100 CRB, Dkt. No. 76 at 6-8 (N.D. Cal. Dec. 20, 2006) (Caire Decl., Ex. 11), Judge Pisano construed “substantially intact” in *Depomed Inc. v. Actavis Elizabeth LLC*, 12-cv-1358 (JAP)(TJB), Dkt. 252 at 18-19 (D.N.J. Jan. 28, 2014) (Caire Decl., Ex. 12), and “substantially all of said drug” in *Depomed, Inc. v. Sun Pharma Global FZE et al.*, 11-3553 (JAP), (D.N.J. Aug. 3, 2012) at 17-21 (Caire Decl., Ex. 17). In each of those cases, both parties’ experts were persons of ordinary skill in the art who were readily able to construe these terms. The fact that several courts and experts have construed similar terms with the “substantial[ly]” language found in the Patents-in-Suit, demonstrates that the patent does not fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention, particularly with respect to claim term “substantially.” It also demonstrates that there is no good cause for Purdue to now seek to add an indefiniteness theory.

The Court’s prior constructions is supported by the intrinsic evidence. For the same reasons set forth in Depomed’s Responsive Claim Construction Brief, the term “substantially all” has a definite meaning to one of skill in the art that is supported by the examples in the specification of the Depomed Patents, relevant

FDA documents, and the constructions of three prior district courts (*Sun, Lupin*, and *Ivax*) and the PTAB. Dkt. 132 at 19-25 (Depomed's Opening Claim Construction Brief). The Federal Circuit has held that terms without reference to a precise measurement are still able to inform one of ordinary skill in the art regarding the scope of the invention. *See Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325, 1335 (Fed. Cir. 2010) (holding claims not indefinite even though the construction of the term "not interfering substantially" defined term without reference to precise numerical measurement).

Moreover, Purdue never appealed the PTAB's construction of "substantially," which were consistent with the district court's constructions of the same terms, even though its appeal was well after the Supreme Court's *Nautilus* opinion. *See* Dkts. 85-1 at 6-7; 85-2 at 6-7; 85-3 at 6-7. The PTAB's ability to construe the terms in light of the specification and Purdue's decision not to appeal the construction to the Federal Circuit highlights Purdue's lack of good cause to amend its invalidity contentions now. As Purdue pointed out to the Court, the PTAB patent judges are "often experienced former patent examiners or patent attorneys with technical training" and thus, would be able to identify if a term is indefinite in construing Depomed's Patents. Dkt No. 83 at 3.

Finally, Purdue cites to cases that do not support its position. These cases do not establish that *Nautilus* represented a change in the law that justifies presenting

entirely new indefiniteness claims for the first time now in the case. Dkt. 129-1 at 7. For example, in *Mycone Dental Supply Co. v. Creative Nail Design, Inc.*, the defendant had already raised indefiniteness theories and was only seeking to supplement its constructions with an expert declaration, as opposed to add a new theory, as Purdue is attempting to do here. No. 11-4380 (JBS/KMW), 2014 WL 3362364, at *4 (D.N.J. July 09, 2014). The other cases Purdue relies upon are inapposite because they all deal with raising new defenses under 35 U.S.C. §101 after the *Alice* case was found to be a “big enough change to justify including a new section 101 argument.” *See* Dkt. 129-1 at 7. Thus, those cases did not address *Nautilus* or the definiteness standard pursuant to 35 U.S.C. § 112. Finally, Purdue does not cite to *any* case law establishing that *Nautilus* is a substantial change in the law to justify amending its invalidity contentions to add a new indefiniteness theory nearly three years after it served its invalidity contentions. Dkt. 129-1 at 3. Thus, Purdue has not good cause to amend its invalidity contentions.

3. Purdue Fails to Demonstrate Diligence in Raising its Proposed Amendment.

Purdue failed to meet its burden of demonstrating its diligence in requesting leave to amend its invalidity contentions. Purdue claims that it could not have raised its specific indefiniteness challenge earlier because it “concluded that it could not succeed in showing that ‘substantially all of said drug’ was not

‘amenable to construction’ or ‘insolubly ambiguous,’” since the term was construed in the *Depomed v. Sun*, No. 11-cv-03553-JAP-TJB litigation. *See* Dkt. 129 at 8. However, this argument is a red herring because diligence and good cause are not established simply because Purdue elected not to assert indefiniteness earlier. *See Nautilus Neurosciences*, 2013 WL 7901901, at *4. Indeed, if Purdue believed the term was indefinite, it should have raised it in its invalidity contentions or in its Federal Circuit appeal of the PTAB’s decisions. There is no explanation why Purdue was purportedly diligent.

Purdue’s requests for a stay based on separate litigations and IPR proceedings, *i.e.*, the *Actavis* and *Endo* litigations and the *Endo* IPRs, in which Purdue claimed would resolve overlapping issues of validity for certain claims of the ‘475 and ‘280 Patents confirm its lack of diligence. *See* Dkt. 77 at 2. Because Purdue was aware of these other proceedings, it knew that, as early as June 13, 2014, Endo and Actavis tried to raise a new indefiniteness theory based on *Nautilus*. *See Depomed, Inc. v. Endo Pharmaceuticals Inc.*, 13-cv-2467 (JAP)(TJB), Dkt. 45 (D.N.J. June 13, 2014) (Caire Decl., Ex. 13)(requesting supplemental *Markman* briefing on *Nautilus*); *see also Depomed Inc. v. Actavis Elizabeth LLC*, 12-cv-1358 (JAP)(TJB), Dkt. 383 (August 25, 2014) (Caire Decl., Ex. 9)(finding under *Nautilus* that the ‘280 Patent is not invalid). Since Purdue was monitoring the issues in other *Depomed* litigations, Purdue knew of this

defense in June of 2014 when the *Nautilus* decision was decided, or at the very least, once the issue was raised in the Endo and Actavis litigations. *See* Dkt. 77. Yet Purdue failed to raise this issue, demonstrating its lack of diligence.

Second, Purdue fails to address why it did not seek to raise this issue earlier. The Supreme Court granted *certiori* in *Nautilus* in January 2014 (before the IPR petitions were filed) and issued its decision in June of 2014, nearly two months before the Court stayed the litigation. Dkt. 89. Purdue knew this issue was before the Supreme Court and decided not to raise it, including in its Federal Circuit appeal of the IPR decisions, even after the Supreme Court issued its decision.

B. Purdue Is Seeking A Ruling On Invalidity Defenses That Are Not And Should Not Be At Issue In this Case

With its Motion, Purdue attempts to sneak several obviousness theories into the case that were never disclosed in its invalidity contentions by requesting the Court determine the “scope” of invalidity contentions remaining in the case under 35 U.S.C. §§ 102, 103. Purdue Motion at 10-17. Purdue’s request effectively amounts to a motion to amend to add invalidity theories, as there is no legitimate grounds for Purdue’s request for “a ruling.” Purdue has not sought leave to add these theories, as is required, because Purdue chose not to disclose them when it could have long ago. L. Pat. R. 3.3, 3.4. As explained in Section D below, which is Depomed’s cross motion and its opposition to the Purdue’s unsupported request for a “ruling,” Purdue has long known about these invalidity theories. Because

Purdue chose not to assert them in the litigation, Purdue should be barred or judicially estopped from pursuing these infirm theories in the case, given the record established during Purdue's IPRs and its representations that the IPRs would narrow the invalidity issues in the litigation.

There are three categories of invalidity theories that Purdue raises in its motion (Purdue's Motion at 17) for which it purports to seek "a ruling" and that is also the subject of Depomed's cross motion to strike, briefed below. The first category is Purdue's anticipation claims based on Baveja, Colombo and the '837 Patent ("Purdue's Anticipation Theories"). These theories were disclosed in the invalidity contentions and in Purdue's IPR petitions. The PTAB rejected them in its decision to institute IPR trials on Depomed's Patents. The second category of invalidity claims is Purdue's obviousness theories that were not specifically disclosed in Purdue's invalidity contentions ("Purdue's Obviousness Theories"). They were raised in Purdue's IPR petitions, but the PTAB rejected them in its decision to institute IPR trials on Depomed's Patents. This second category are all of Purdue's obviousness theories for the asserted claims. The third category is Purdue's obviousness theories for Claims 11 and 12 that were in its invalidity contentions but not raised before the PTAB, where Purdue argued that these claims were allegedly obvious over Kim in view of the '453 patent ("Theories Regarding Claims 11 and 12").

Purdue's failure to address the motion to amend requirements for Purdue's Obviousness Theories that were not disclosed in its invalidity contentions is sufficient grounds to bar Purdue from adding them into the case now. For these obviousness theories, Purdue did not provide in its invalidity contentions with the requisite notice how the specific combinations of purported prior art rendered Depomed's asserted claims obvious. For example, for Claims 1, 8, 9, 13, 14, 45 and 46 of the '280 Patent, Purdue never specifically disclosed the combination of Colombo with the '837 Patent and the '548 Patent. Dkt. No. 129-2, Ex. A (Purdue's Invalidity Contentions) at 91-96. In other words, Purdue never identified which specific portions of these references matched the elements of the asserted claims. *Id.* Purdue also never identified what elements of Claims 43, 54, 55, 57, 58 and 66 of the '475 Patent were addressed by specific portions of the '803 Patent, Baveja and Colombo. Purdue failed to even disclose Baveja and Colombo for claims 54 and 55. Dkt. No. 129-2, Ex. A at 51-75.

Given that Purdue never provided the requisite disclosures for these obviousness theories, Purdue is not entitled to have these theories in the case. Even if Purdue were to attempt to seek to amend its invalidity contentions now, Purdue could not demonstrate diligence or good cause because Purdue has known about these theories since it presented them to the PTAB in 2014. Moreover, the PTAB determined that Purdue's Obviousness Claims were not grounds to institute

a trial before the PTAB, proving that Purdue has no good cause to seek to add them now, as they did not merit IPR review under the PTAB's lower standards of review. *See* Dkts. 85-1 at 25; 85-2 at 24; 85-3 at 21. Thus, for the reasons set forth here and below in Section D, Purdue should be precluded from presenting these Obviousness Theories.

C. Purdue's Proposed Amendments Will Prejudice Depomed

As a preliminary matter, the Court need not even reach the prejudice issue here because Purdue has no good cause to amend and has failed to establish that it has been diligent. *O2 Micro Int'l Ltd., v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1368 (Fed. Cir. 2006) (concluding that it did not "need to consider the question of prejudice" because the "district court could properly conclude" a lack of diligence.). Furthermore, Depomed will be unduly prejudiced if any amendments are permitted. Based on Purdue's stated invalidity claims, which included its claims presented before the PTAB in its IPR petitions, Depomed developed a successful strategy to defeat Purdue's invalidity claims with the understanding that the IPRs would substantially streamline the invalidity issues in the case. Depomed's understanding was based on Purdue's explicit representations that the end result of the IPRs would be narrowing of the issues and that Purdue was taking thoughtful steps in electing its invalidity claims to raise in the IPR proceedings, which would not overlap with the claims it preserved for the

litigation. *See* Dkt. 80 (Purdue's Letter of April 30, 2014 at 2); *see also* Dkt. 76 (April 11, 2014); Dkt. 77 (April 21, 2014); Dkt. No. 83 (May 5, 2014); Dkt No. 88 (July 21, 2014). In fact, the Court granted Purdue's multiple requests to stay, based upon Purdue's numerous representations that the IPRs will narrow the invalidity issues and the IPR proceedings would promote efficiency and simplify the case. *Id.* Thus, Depomed has already experienced a substantial delay in the progression of this case against Purdue, based on Purdue's claims that the IPRs would reduce the invalidity issues in the case.

Purdue's proposed amendment would unduly prejudice Depomed because it expands Purdue's invalidity case. Depomed will be forced to, yet again, expend significant time and resources to defend against Purdue's anticipation and obviousness invalidity theories, which the PTAB already determined did not merit IPR review. Depomed will need to seek fact and expert discovery into these additional issues.

Additionally, Depomed anticipates that Purdue will use a grant of adding invalidity claims into the case as a basis for further delaying the case schedule, despite the fact that Depomed has already faced a two year delay in the litigation. It would be unduly prejudicial to require Depomed to defend against another set of invalidity challenges after Depomed successfully defeated Purdue's IPRs,

particularly given Purdue's representations that irrespective of the outcome of the IPRs, the case would be streamlined.

Furthermore, Depomed will be prejudiced if it has to defend, at this stage of the litigation, Purdue's indefiniteness theory and Purdue's Obviousness Combinations that it could have been identified in its invalidity contentions three years ago because Purdue knew about when it served its invalidity contentions and were theories that the PTAB rejected and Purdue elected not to disclose in its invalidity contentions. Depomed will be severely prejudiced if it has to engage in an undertaking of comparable, if not greater, magnitude at this stage of the case to defend against these theories.

Furthermore, allowing Purdue to amend its invalidity contentions now would obliterate the goal of "crystallizing" parties' theories early in the case. *Nautilus Neurosciences*, 2013 WL 7901901, at *6-7 (denying motion to amend invalidity contentions to add an indefiniteness defense and four new prior art references due to prejudice to the patentee who "would be required to expend significant resources in analyzing the new references and evaluating how to structure their case in light of the inclusion thereof, all the while delaying the resolution of this dispute.")). Similarly, Depomed would be required to have to analyze and defend against combinations of prior art not disclosed in Purdue's invalidity contentions, as well as address a newly minted and unsupported

indefiniteness claim. Given the substantial prejudice that would result if Depomed had to address an expanded invalidity case after the IPRs and two year stay, Purdue's Motion and "request for ruling" should be denied.

D. Depomed's Cross-Motion To Strike Purdue's §§ 102 And 103 Challenges is Substantially Justified Based On Statutory And Judicial Estoppel And for Failure to Comply with Patent Local Rule 3.3.

In its Motion and during the parties' meet and confers, Purdue asserted that it intends to pursue certain alleged invalidity theories in the case. *See* Dkt. No. 129 (Motion) at 11 and 17. Depomed seeks to strike several of Purdue's invalidity theories for the following reasons: (1) Purdue failed to meet the disclosure requirements under the Local Patent Rules for its invalidity contentions under 35 U.S.C. §103, §102(b), and §102(g); (2) Purdue's §102(b) and §102(g) claims, and its obviousness combinations for Claims 11 and 12 that were disclosed in its invalidity contentions are statutorily barred because they reasonably could have been raised to the PTAB in the IPRs; (3) Purdue should be barred from presenting "new" invalidity theories after representing that the IPRs would necessarily streamline the invalidity case and where the PTAB determined such theories did not merit review under its lower standards of review for IPRs; and (4) Purdue should not be permitted to re-litigate combinations of prior art the PTAB already considered because it would be a waste of judicial resources and would result in substantial prejudice to Depomed.

1. Depomed's Motion to Strike Should be Granted because Purdue's Remaining Invalidity Contentions Do Not Comply with Local Patent Rule 3.3(b).

Purdue's invalidity contentions should be struck as non-compliant with Local Patent Rule 3.3(b), for failing to identify with any particularity the invalidity arguments it seeks to raise in its proposed amendment. Specifically, pursuant to the Local Patent Rules, Purdue was required to identify *all* of its invalidity theories, including each prior art reference it intended to rely upon in the litigation, including, *inter alia*, "an explanation of why the prior art reference renders the asserted claim obvious," "identification of any combinations of prior art showing obviousness," and the identities of the persons and circumstances surrounding any challenges brought under 35 U.S.C. § 102 (b)(f)(g). L. Pat. R. 3.3.

Purdue's shifting-sands approach to its invalidity claims are precisely the sort of tactic addressed by Local Patent Rule 3.3(b), which requires that Purdue's invalidity contentions provide meaningful notice of the invalidity claims it intends to advance. Purdue should not be allowed to ambush Depomed with claims that were never properly disclosed in its contentions.

As discussed above, Purdue should not be allowed to amend its invalidity contentions to fix its deficiencies or add combinations. Patent Rules "are designed to require parties to crystallize their theories of the case early in the litigation and to adhere to those theories once they have been disclosed." *King Pharms., Inc. v.*

Sandoz, Inc., No. 08-5974 (GEB), 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). Because the Rules favor early disclosure, motions to amend invalidity contentions are granted only for good cause shown, something that Purdue has failed to even address. *See AstraZeneca AB v. Dr. Reddy's Labs. Inc.*, No. 11-2317 (JAP), 2014 WL 1292226, at *5 (D.N.J. Mar. 28, 2014) (denying motion to amend where the “length and nature of Plaintiffs' proposed amendments... [did] not suggest inadvertent omission”, but rather “reflect[ed] a shift in theory or position by Plaintiffs.”) (internal quotation omitted).

a. Purdue's obviousness contentions fail to comply with local rules and should be struck.

Purdue's obviousness theories are deficient under Local Patent Rule 3.3(b) because they were not disclosed in Purdue's invalidity contentions. Purdue failed to provide “an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness.” *See* L. Patent R. 3.3(b). Despite Purdue's explicit agreement in 2013 that the only obviousness combinations that Purdue was pursuing in the case were those ***specifically*** disclosed in its invalidity contentions, Purdue is now seeking to pursue these obviousness combinations that were not disclosed in its invalidity contentions. These combinations, which the PTAB determined did not merit IPR review, are as follows:

- Claim 10 of the '475 and '280 Patents allegedly obvious over Colombo, Kim, the '837 patent and the '548 patent;
- Claims 1, 8, 9, 13, 14, 45, and 46 of the '280 Patent allegedly obvious over Colombo, the '837 patent and the '548 patent;
- Claims 43, 54, 55, 57, 58, and 66, of the '475 Patent allegedly obvious over the '803 patent, Baveja, and Colombo.

Purdue tries to justify its belated attempt to sneak these combinations in by pointing to several tables in its invalidity contentions that list dozens of prior art references. *See* Dkt.129 (Purdue's Motion to Amend) at 15-17. However, these tables do not comply with the Local Rule requirements. They do not provide any information regarding how the references would be combined or how a person of ordinary skill in the art would be motivated to do so. *See, e.g., See* Dkt. 129-2,Ex. A at 71-73; 127-128. Moreover, Purdue confirmed earlier in 2013 that it would not be pursuing these theories which were not specifically disclosed in its invalidity contentions. Purdue confirmed, in response to Depomed's inquiries, that it intended to only rely upon the obviousness arguments described in detail in the body of its contentions. *See* Caire Decl., Ex. 7. Depomed relied upon Purdue's representations and did not seek to strike Purdue's contentions at that time. Now that Purdue has reversed its position and has requested "a ruling" that they are still in the case, Depomed is seeking to strike these undisclosed theories.

Furthermore, Purdue's invalidity contentions, which span 359 pages and contain hundreds of prior art references, did not and could not have put Depomed

on notice of the specific obviousness theories it now advances. Dkt. No. 129-2, Ex. A. At this stage, to allow Purdue to concoct an entirely new set of obviousness theories would result in severe prejudice to Depomed. Purdue cannot be permitted to disregard the disclosure requirements of the local rules. Thus, the court should strike the following obviousness combinations:

- the combination of Colombo, Kim, the '837 patent and the '548 patent for Claim 10 of the '475 and '280 Patents;
- the combination of Colombo, the '837 patent and the '548 patent for Claims 1, 8, 9, 13, 14, 45, and 46 of the '280 Patent; and
- the combination of the '803 patent, Baveja, and Colombo for Claims 43, 54, 55, 57, 58, and 66, of the '475 Patent.

b. Purdue's theory of anticipation by MS Contin® under §102(b) was not disclosed in compliance with local rules, is barred by statutory estoppel and should be struck.

Purdue's invalidity contentions also fail to sufficiently disclose their anticipation theory that MS Contin anticipates the following claims under 35 U.S.C. § 102(b): claims 1, 8, 9, 13 and 14 of the '475 and '280 Patents, and claims 45 and 46 of the '280 Patent. All that Purdue discloses is the following: "[i]n 1984, more than one year prior to the alleged invention, Purdue Pharma L.P. first offered the prescription medication MS Contin® controlled-release morphine sulphate tablets for sale in the United States." Dkt. 129-2, Ex. A at 46. This disclosure, however, does not meet the requirements of the local rules. Purdue

failed to identify the specific item offered for sale or publicly used or known, the date the offer or use took place or the information became known, and the identity of the person or entity which made the use or which made and received the offer, or the person or entity which made the information known or to whom it was made known. L. Pat. R. 3.3. The failure to provide this requisite information is grounds to strike this theory given its woefully deficient disclosure.

Purdue also failed to properly disclose the sale of MS Contin® that it now seeks to rely on for its invalidity claims. Allowing them to assert this theory now would result in severe prejudice to Depomed given Purdue's lack of disclosure regarding facts related to the purported circumstances of the offer for sale. Depomed would be forced to seek discovery into basic facts that Purdue was required to disclose when it served its invalidity contentions, such that it could assess the merits of Purdue's claims. Certainly, such a claim would have impacted Depomed's decision regarding which claims to assert against Purdue and potentially have raised claim construction issues.

Moreover, Depomed relied on Purdue's representations that the IPRs would streamline the invalidity issues in this case by resolving Purdue's invalidity claims. Now that Purdue has lost the IPRs, it is seeking expand its invalidity case to include claims it failed to properly disclose in its invalidity contentions. Therefore, Purdue's 102(b) claims relating to MS Contin should be struck.

c. Purdue's 35 U.S.C. § 102(g) contention is deficient.

Purdue's invalidity contentions are similarly deficient with respect to its new claim that the asserted claims of the '475 and '280 Patent are also invalid under 35 U.S.C. § 102(g). Purdue alleges that the claims are invalid because the claimed oral dosage forms and methods were made in this country "by another inventor who had not abandoned, suppressed, or concealed [them]." *See* Dkt. 129, Ex. A at 187-89. Pursuant to the local rules, however, in order to properly disclose claims under 35 U.S.C. § 102(g), Purdue's contentions must have identified the identities of the person(s) or entities involved in and the circumstances surrounding the making of the invention before the patent applicant(s). L. Pat. R. 3.3. Purdue's failure to disclose this information in its contentions is fatal to its claim now that it is seeking to pursue this defense. Once again, Depomed is prejudiced because Purdue has failed to provide fundamental information regarding this claim and thus, has been prevented from seeking appropriate discovery into such a claim. Thus, the Court should strike this contention.

2. Purdue is Barred by Statutory Estoppel from Raising Invalidity Arguments it Could and Should Have Raised in the IPR.

Purdue's invalidity theory relating to MS Contin, its §102(g) claim and theories regarding Claims 11 and 12, described below, are statutorily barred because Purdue could have raised them in its IPRs, but failed to do so. The

estoppel provisions of 35 U.S.C. § 315(e) provide that where a party challenges the asserted claims in an IPR proceeding, it must raise its invalidity claims at the IPR proceeding. After the IPR, the party is estopped from challenging the validity of the claims on “any ground that the petitioner raised or reasonably could have raised during that inter partes review.” 35 U.S.C. § 315(e)(2).

Purdue is statutorily estopped from relying on the sale of MS Contin as anticipatory art because Purdue should have, but failed to raise that theory in its IPRs. A challenger can raise any invalidity challenge under 35 U.S.C. §§ 102 or 103 that rely on “patents or printed publications” in the IPR Petition. *See* 37 C.F.R. § 42.104(b)(2) (IPR Petition should include “[t]he specific statutory grounds under 35 U.S.C. §§ 102 or 103 on which the challenge to the claim is based and the patents or printed publications relied upon for each ground”).

Purdue was aware of the MS Contin product at least as early as September 3, 2013, when it served its invalidity contentions. As a result, Purdue had printed publications about the product at least three months before filing its IPR requests. *See, e.g.*, Dkt. 129, Walsh Decl., Ex. A at 86-87 (Invalidity Contentions).

Specifically, with its invalidity contentions in September of 2013, Purdue produced a product data brochure and package insert information for MS Contin. *See* Caire Decl., Ex. 14. These documents are printed publications that could have been raised before the PTAB. *See In re Wyer*, 655 F.2d 221, 226 (C.C.P.A. 1981) (A

reference is proven to be a “printed publication” . . . “upon a satisfactory showing that such document has been disseminated or otherwise made available to the extent that persons interested and ordinarily skilled in the subject matter or art, exercising reasonable diligence, can locate it.”) (citations omitted); *see also Cumberland Pharms., Inc. v. Mylan Institutional LLC*, 137 F.Supp.3d 1108, 1122-24 (N.D. Ill. Oct. 2, 2015) (defendants relying on package insert as printed publication under 35 U.S.C. § 102). Purdue had all the documentation it needed to raise its 35 U.S.C. § 102(b) theory before the PTAB based on MS Contin and elected not to do so. Purdue is, therefore, statutorily estopped from relying on it in this proceeding.

For the same reasons, Purdue is also statutorily estopped from arguing that the asserted claims of the ‘475 and ‘280 Patent are invalid under 35 U.S.C. § 102(g). Purdue’s sole basis for this contention is based on the ‘963 patent and the ‘623 provisional application of James W. McGinity. *See* Dkt. 129-2, Ex. A at 21 (Invalidity Contentions for 102(g)). Both of these documents are printed publications that Purdue had in its possession months before it filed its IPR requests, as Purdue produced them with its invalidity contentions in September of 2013. *See* Caire Decl., Exs. 15, 16; MPEP §2128, quoting *In re Wyer*, 655 F.2d at 226. Purdue could have and should have raised its 102(g) claim before the PTAB. Because it elected not to do so, Purdue is statutorily barred from raising it now. 35

U.S.C. § 315(e). Finally, Purdue is attempting to assert obviousness theories for Claims 11 and 12 of the '475 and '280 Patents which it could have, but elected not to raise in its IPR requests. Specifically, Purdue alleges that Claims 11 and 12 are invalid as obvious over Kim in view of the '453 patent. This obviousness challenge should have been made in Purdue's IPRs, but Purdue opted not to raise it. Purdue is therefore statutorily estopped from arguing obviousness over Kim and the '453 patent. 35 U.S.C. § 315(e).¹

3. Purdue Should be Judicially Estopped from Re-Litigating its Invalidity Positions, Based on its Prior Representations to the Court in Support of its Request for a Stay.

Purdue should be precluded from re-hashing its IPR invalidity arguments based on judicial estoppel. Judicial estoppel bars litigants from “playing fast and loose with the courts.” *United States v. Esperanza-Vasquez*, 211 F. App'x 140, 142 (3d Cir. 2007) (finding that judicial estoppel applied to bar defendant from challenging an order that he sought and did not contest until he failed to comply with its terms.) (citations and internal quotations omitted). Judicial estoppel applies where (1) the party's position in the course of litigation is “clearly inconsistent” with an earlier position; (2) whether a court adopted the earlier position such that acceptance of the later position would create the perception that

¹ Purdue raised different combination with respect to claims 11 and 12 but should not be allowed to raise them in the litigation because they were not disclosed in its invalidity contentions.

the court was “misled”, and (3) whether the party asserting the inconsistent position would “derive an unfair advantage or impose an unfair detriment on the opposing party not estopped.” *Id.* at 142, citing *New Hampshire v. Maine*, 532 U.S. 742, 121 S.Ct. 1808.

Here, Purdue should be judicially estopped from changing its position regarding the estoppel effect of the IPRs and its representation that the IPRs would necessarily streamline the invalidity issues in this case. The idea that Purdue could augment its invalidity theories in this case after a two year stay of the litigation and Purdue represented numerous times the IPRs would narrow the issues certainly creates a perception that Purdue simply paid lip service to the estoppel effect of the IPRs and how they will streamline the litigation.

To obtain a stay pending resolution of its IPR claims, Purdue repeatedly represented to the court that “the issues for trial in the present action would be simplified” by the stay “because Purdue would be estopped from re-litigating the validity of those claims” on grounds it raised or could have raised in its then-pending IPRs. *See* Dkt. 80 (Letter of April 30, 2014 at 2); *see also* Dkt. 76 (April 11, 2014), Dkt. 77 (April 21, 2014), Dkt. No. 83 (May 5, 2014), Dkt No. 88 (July 21, 2014). Notably, the Court reasoned that the IPR proceedings would have an estoppel effect on Purdue when it granted the stay pending a final decision on the IPRs. Dkt. No. 89 at 11.

Furthermore, as described herein, Depomed will be prejudiced if Purdue is allowed to introduce invalidity challenges that it failed to raise or disclose earlier despite knowing about such theories, as they were ones that IPR determined were not worthy of IPR review after enduring a two year stay.

Given these facts, Purdue should be judicially estopped from presenting the specific theories identified below. Purdue should be precluded from re-litigating the invalidity contentions under 35 U.S.C. §102/§103 it identifies in its motion to amend (Dkt. 129 (Purdue Motion to Amend) at 17) because (1) Purdue should be barred from asserting invalidity theories based on their representation that the IPR would simplify issues, and (2) Purdue's theories are duplicative of the claims already disposed of in Purdue's IPR proceedings and re-litigating these claims would be a waste of judicial resources. The combinations of art Purdue now urges the court review are nearly identical to what was raised in the IPRs, as discussed in detail below.

a. Anticipation theories based on Baveja and Colombo.

Purdue seeks to assert that claims 1, 8, 9, 13, 14, 45 and 46 of the '280 patent and claims 1, 8, 9, 13, 14 and 61 of the '475 patent are anticipated by Baveja and Colombo. Purdue should be precluded from litigating these theories. First, Purdue challenged the exact same claims on the grounds that Baveja was anticipatory and the Board declined to institute on the grounds that Purdue failed to establish a

likelihood of success on these grounds. Dkt. No. 85-2 at 12 and 15 (Declining to institute on anticipation grounds for claims 1, 8, 9, 13, 14 and 61 of the ‘475 Patent in light of Baveja and Colombo, respectively, because “Petitioner has not shown that Baveja teaches the ‘substantially intact’ limitation of Claim 1” and “Petitioner has not shown that Colombo inherently teaches the ‘upon immersion in gastric fluid’ limitation of claim 1)); *Id.*, Dkt. No. 85-1 at 12 and 15 (Declining on the same grounds for 1, 8, 9, 13, 14, 45, or 46 of the ‘280 Patent)). Given this finding alone, Purdue should be barred from raising its anticipation claims, given its representations that it would be estopped from duplicating unsuccessful theories presented in the IPRs.

Second, the Board instituted review on Purdue’s obviousness arguments that included Baveja and Colombo and rejected Purdue’s arguments using these references in combination with other references. Specifically, the Board instituted Purdue’s obviousness arguments against 1, 8, 9, 13, 14, 61 and 62 of the ‘475 Patent using combinations of art that included Baveja and Colombo. *See* Dkt. No. 85-2 at 25 (grounds (A) and (C))). The Board also instituted Purdue’s obviousness arguments against 1, 8, 9, 13, 14, 61 and 62 of the ‘280 using combinations of art that included Baveja. *See* Dkt. No. 85-1 at 25 (ground (A)). While Colombo was not instituted as part of the obviousness combinations against the ‘280, the Board expressly noted that it found Purdue’s combinations relying on Colombo in place

of Baveja to be “redundant” in light of the Baveja combinations, and declined to institute the Colombo combinations for that reason. *Id.*

The Board fully considered the Baveja and Colombo references and found that they did not render the currently-asserted claims obvious, even when combined with other prior art. The PTAB, utilizing the broadest reasonable construction and the lower preponderance of evidence standard for validity, determined that a combination of these references do not disclose all the elements of the asserted claims. Given the PTAB’s rejection of these references as anticipatory and finding that they did not render the claims obvious, Purdue should be judicially estopped from arguing that Baveja and Colombo anticipate the asserted claims to avoid wasting unnecessarily the Court’s resources on issues already addressed in the IPRs.

b. Anticipation theories based on the ‘837 Patent.

Purdue also seeks to revive its anticipation arguments against Claims 43, 57 and 58 of the ‘475 and claim 43 of the ‘280 Patent. The PTAB, however, found that Purdue failed to show sufficiently that the ‘837 patent discloses each limitation of the challenged claims and declined to institute trial on the anticipation ground based on the ‘837 patent. The ‘837 was also considered in combination with other prior art in connection with Purdue’s obviousness theories and the PTAB instituted trial for the ‘475 and the ‘280 Patents. *See* Dkt. No.85-3 at 22 (Ground B, ‘837 in

combination with Baveja and Colombo against, inter alia, Claim 43 of the ‘475)); *see also id.*, Dkt. No. 85-1 at 25, Ground C (the ‘837 patent in combination with Baveja and Colombo against Claim 43 of the ‘280)). Ultimately, the PTAB rejected Purdue’s obviousness theories, in combination with other prior art and did so under the less stringent legal standard the PTAB is required to use for its invalidity reviews. Given these PTAB determinations, Purdue should be judicially estopped from arguing that they anticipate Depomed’s Patents and force the parties and Court to unnecessarily waste judicial resources on issues already addressed in the IPRs.

c. Obviousness theories for claims 11 and 12 of Depomed’s Patents.

Purdue’s attempt to evade the estoppel effect of the IPRs on its theories for claims 11 and 12 is in direct contradiction of its July 11, 2014 representation to the Court that the IPRs would simplify the validity issues as to Claims 11 and 12 of Depomed’s Patents because “they include all the same limitations as [Claim 1 of the ‘475 Patent and Claim 1 of the ‘280 Patent]” which the PTAB “found a reasonable likelihood that Purdue would be able to establish invalidity.” Dkt No. 85 at 1-2. In fact, Purdue emphasized this claim again in its July 21, 2014 briefing, representing that “[I]n any event, the PTAB’s resolution of invalidity of the claims from which claims 11 and 12 depend will plainly simplify any remaining validity issues for claims 11 and 12.” Dkt No. 88 at 3. Purdue should be judicially

estopped from attempting to re-litigate these claims given the representations it made regarding how the IPRs will narrow the issues in the case.

d. Purdue attempts to re-litigate the same obviousness theories.

Purdue should also be precluded from challenging the asserted claims based on the same obviousness theories that the PTAB already considered. Specifically, Purdue should be estopped from presenting the following obviousness theories which the PTAB determined did not warrant review in an IPR trial:

- The combination of Colombo, the '837 patent and the '548 patent for Claims 1, 8, 9, 13, 14, 45, and 46 of the '280 Patent;
- The combination of the '475 patent, the '803 patent, Baveja and Colombo for Claims 43, 54, 55, 57, 58, and 66 of the '475 Patent;
- The combination of Colombo and Kim with the '837 patent and the '548 patent for Claim 10 of Depomed's Patents.

Dkt. 129-1 at 17. The PTAB found these combinations redundant of obviousness theories that Purdue presented and in which the PTAB instituted review.

In seeking to add these invalidity theories into the case, Purdue is attempting to re-litigate the obviousness theories that the PTAB already determined did not warrant review. As such, Purdue should be judicially estopped from asserting the same obviousness theories the PTAB already reviewed and determined did not impact the invalidity of Depomed's Patents.

Purdue wishes to re-litigate whether claims 1, 8, 9, 13, 14, 45 and 46 are obvious over Colombo, the '837 patent and the '548 patent. Dkt. 129-1 at 17. The PTAB considered these references during the IPRs. The PTAB found that “the remaining grounds challenge the same claims as those previously discussed, but rely on Colombo as the primary reference instead of Baveja,” which was “redundant” in light of its institution of Purdue’s obviousness claim based on the combination of Baveja with the '837 patent and the '548 patent. *See* Dkt. 85-2 at 25.

Purdue also seeks to re-litigate its obviousness theory that claims 43, 54, 55, 57, 58 and 66 are invalid in light of the '803 patent in combination of Baveja and Colombo. Dkt. 129-1 at 17. The Board considered this combination and expressly declined to institute on this very theory because Purdue had already presented and the PTAB had already considered each of the prior art in the combination with respect to each of the challenged claims, such that the combination was “redundant.” *See* Dkt. 85-3 at 21.

Finally, the PTAB also found Purdue’s theory against Claim 10 of the '475 and '280 Patents based on the combination of Colombo and Kim with the '837 patent and the '548 patent redundant. Dkt. 129-1 at 17. The PTAB considered challenges to Claim 10 based on the same prior art and found this theory to be redundant of Purdue’s obviousness theory for the same claim based on the

combination of Baveja and Kim with the '837 patent and the '548 patent. The PTAB repeatedly found Purdue's combinations substituting Colombo for Baveja to be redundant.

Purdue's attempt to re-litigate the same obviousness theories by replacing one reference with a functionally identical reference in a combination should be rejected. Retrying these issues will unnecessarily require precious judicial resources. Further, Purdue should be judicially estopped from presenting these duplicative claims after insisting that the IPRs would streamline the invalidity issues in the litigation. Purdue should not be permitted to make misleading representations without consequence about the estoppel effects and efficiencies that Purdue represented to the Court the IPRs would necessarily provide, only to then claim that the estoppel does not apply to its invalidity theories.

IV. CONCLUSION

For the foregoing reasons, Depomed respectfully requests denial of Purdue's Motion and an order striking Purdue's invalidity contentions identified herein.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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